

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

January 5, 2015

Sonoscape Company Limited % Mrs. Toki Wu Regulatory Affairs Manager Yizhe Building, Yuquan Road, Nanshan Shenzhen 518051 P.R. CHINA

Re: K142710

Trade/Device Name: S9 Portable Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: September 18, 2014 Received: December 1, 2014

Dear Mrs. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (if known)	
K142710	
Device Name S9 Portable Digital Color Doppler Ultrasound System	
Indications for Use (Describe)	
The SonoScape S9 system is a general-purpose ultrasonic image evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, I (neonatal and adult), Trans-esoph.(Cardiac), Laparoscopic, OB	, testes, thyroid), Cephalic (neonatal and adult), Trans- Musculo-skeletal (Conventional and Superficial), Cardiac
Type of Use (Select one or both, as applicable)	
Prescription Use (Part 21 CFR 801 Subpart D)	☐ Over-The-Counter Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE – Co	ONTINUE ON A SEPARATE PAGE IF NEEDED.
FOR FDA U	SE ONLY
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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System: SonoScape S9

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	se. Diagnostic ultrasot	_				Tr analysis	7 01 010 1101110	an body do	101101101
Clinical App	lication	Mc	de d	of Opera	tion				011 *
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic	Ν	Ν	N		N	N	Note 1	Notes 2,4
	Pediatric	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,6,7
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Fetal	Adult Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Imaging&	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Other	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Cardiac Adult	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Cardiac	Intravascular(Cardiac)								
Carulac	Trans-esoph.(Cardiac)	Ν	Ν	Ν	N	N	N	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р	N	Р	Р	Note 1	Notes 2,4
Vessel	Cerebral vascular			N					

N = new indication;	P = previo	usly cl	eared by	FDA;	E = ad	ded under th	is appendix	
Note 1: Other Combined	l includes: B	/M; B/P	WD; B/TI	HI; M/Co	lor M; B/Co	lor Doppler; E	B/Color Dopp	oler/PWD;
B/Power Doppl	er/PWD							
Note 2: Tissue Harmoni	c Imaging. T	he feati	ure does	not use	contrast age	ents		
Note 3: TDI	Note 4: 3D		1	Note 5: 4	D			
Note 6: Small Organ: br	east, thyroid	, testes						
Note 7: Elastography								

	(Division Sign Off) ion of Radiological Health Diagnostic and Radiological Health
 510(k)	K142710

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Transducer: C322 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	is-ti					· analysis			
Clinical App	ilcation	IVIC	de d	of Opera	tion		D	Γ	041*
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)					_			
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								
N = new inc	lication; P = previo	usly	cle	ared by	FDA;	E = ad	ded under th	is appendix	
Note 1: Other	er Combined includes: E	/M; I	B/P\	ND; B/TI	H; M/Co	lor M; B/Co	olor Doppler; I	3/Color Dopp	oler/PWD;
B/F	Power Doppler/PWD								
Note 2: Tiss	ue Harmonic Imaging. 1	he fe	eatu	re does	not use	contrast ag	ents		
Note 3: TDI	Note 4: 3D			1	Note 5: 4	.D			
Note 6: Sma	ıll Organ: breast, thyroic	, tes	tes						
Note 7: Elas	tography								
				(Division	on Sign	Off)			
		D	ivisi	on of R	adiologi	cal Health			
	Office of	In \	/itro	Diagno	stic and	d Radiolog	ical Health		
	510(k) _		K14	<u> 12710 </u>				

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Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Clinical App	lication			of Opera					
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Candina	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Vessel	Cerebral vascular							
N = new inc	lication; P = previo	usly cle	eared by	FDA;	E = ad	ded under th	is appendix	
Note 1: Othe	er Combined includes: B	/M; B/P\	ND; B/TI	H; M/Co	lor M; B/Co	lor Doppler; E	B/Color Dopp	oler/PWD;
B/F	ower Doppler/PWD							
Note 2: Tiss	ue Harmonic Imaging. T	he featu	re does	not use	contrast ag	ents		
Note 3: TDI	Note 4: 3D		1	Note 5: 4	D			
Note 6: Sma	II Organ: breast, thyroid	, testes						
Note 7: Elas	tography							
			(Division	on Sign	Off)			
		Divisi	ion of R	adiologi	cal Health			
	Office of	In Vitro	Diagno	stic and	d Radiolog	ical Health		
	510(k)	K14	12710				
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Transducer: C353 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	de d	of Opera	tion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other									
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	lication; P = previous Combined includes: Be ower Doppler/PWD ue Harmonic Imaging. Tote 4: 3D Note 4: 3D III Organ: breast, thyroid tography	/M; i	B/P\ eatu	ND; B/Ti re does	HI; M/Co	lor M; B/Co contrast ag		
	Office of 510(In \		on of Ra Diagno	_	cal Health	jical Health	

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Transducer: C542 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Mc	ode o	of Opera	tion	-			
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
Tra	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Candina	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	lication; P = previous Combined includes: Be ower Doppler/PWD ue Harmonic Imaging. Tote 4: 3D Note 4: 3D III Organ: breast, thyroid tography	/M; he f	B/P\ eatu	ND; B/Ti re does	HI; M/Co	lor M; B/Co contrast ag		
	Office of 510(In \		on of R	_	cal Health	jical Health	

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Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	lise: Diagnostic ultraso								
Clinical App General	ICALION	IVIC	oue (of Opera	uon		Power		Other*
(TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	(Amplitude) Doppler	Other* Combined	Specify
Ophthalmic	Ophthalmic								
	Fetal	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,5
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Candiaa	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								
N = new inc	lication; P = previo	usly	/ cle	eared by	FDA;	E = ad	ded under th	is appendix	
Note 1: Other	er Combined includes: B	/M; I	B/P\	ND; B/TI	H; M/Co	lor M; B/Co	lor Doppler; I	3/Color Dopp	oler/PWD;
B/F	Power Doppler/PWD								
Note 2: Tiss	ue Harmonic Imaging. T	he f	eatu	re does	not use	contrast ag	ents		
Note 3: TDI	Note 4: 3D			1	Note 5: 4	.D			
Note 6: Sma	all Organ: breast, thyroid	, tes	tes						
Note 7: Elas	tography								
				(Division	on Sign	Off)			
		D	ivisi	on of R	adiologi	cal Health			
	Office of	In \	/itro	Diagno	stic and	d Radiolog	ical Health		
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Transducer: C613 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	lication								
Clinical App General	lication	IVIC	ode d	of Opera	tion		Power		Other*
(TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	(Amplitude) Doppler	Other* Combined	Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Ν	Ν	Ν		Ν	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	Ν	Ν	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	Ν	N	N	N	N	N	Note 1	Notes 2,3,4
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric	Ν	N	N	N	N	N	Note 1	Notes 2,3,4
Cardina	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

N = I	new indication;	P = previously	cleared by FDA;	E = added under this appendix
Note	1: Other Combined	d includes: B/M; B	s/PWD; B/THI; M/Color	M; B/Color Doppler; B/Color Doppler/PWD;
	B/Power Dopp	ler/PWD		
Note	2: Tissue Harmoni	c Imaging. The fe	ature does not use conf	trast agents
Note	3: TDI	Note 4: 3D	Note 5: 4D	

Note 6: Small Organ: breast, thyroid, testes

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Division of Radiological Health	
Office of In Vitro Diagnostic and Radiological Hea	th
510(k) <u>K142710</u>	

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Transducer: 2P2 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	ode o	of Opera	tion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Fetal	Adult Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Cardiac	Intravascular(Cardiac)								_
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Vessel	Cerebral vascular								Ì
N = new ind	lication; P = previo	usly	/ cle	eared by	FDA;	E = ad	ded under th	is appendix	
Note 1: Othe	er Combined includes: B	/M; I	B/P\	ND; B/TI	H; M/Co	lor M; B/Co	lor Doppler; I	3/Color Dopp	oler/PWD;
B/F	ower Doppler/PWD								
Note 2: Tiss	ue Harmonic Imaging. T	he fe	eatu	re does	not use	contrast ag	ents		
Note 3: TDI	Note 4: 3D			1	Note 5: 4	D			
Note 6: Sma	II Organ: breast, thyroid	, tes	tes						
Note 7: Elas	tography								

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Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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Transducer: 3P1 Phase Array

Diagnostic Ultrasound Transducer

Clinical App	lication	Мс	ode o	of Opera	tion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Fetal	Adult Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Cardina	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Vessel	Cerebral vascular							
N = new inc	lication; P = previo	usly cl	eared by	FDA;	E = ad	ded under th	is appendix	
Note 1: Other	er Combined includes: B	/M; B/P	WD; B/T	HI; M/Co	olor M; B/Co	olor Doppler; I	3/Color Dopp	oler/PWD;
	Power Doppler/PWD							
	ue Harmonic Imaging. T	he featı			_	ents		
Note 3: TDI	Note 4: 3D		ı	Note 5: 4	·D			
	Ill Organ: breast, thyroid	, testes						
Note 7: Elas	tograpny							
			(Division	on Sign	Off)			
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Transducer: 5P2 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication			of Opera	tion			-	
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
0!:	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

i elipilelai	i cripriciai vessei							
Vessel	Cerebral vascular							
N = new inc	lication; P = previo	usly o	cleared by	/ FDA;	E = ad	ded under th	is appendix	(
	er Combined includes: B	/M; B/	PWD; B/T	HI; M/Cc	olor M; B/Co	olor Doppler; I	3/Color Dopp	oler/PWD;
	Power Doppler/PWD							
	ue Harmonic Imaging. T	he fea			•	ents		
Note 3: TDI	Note 4: 3D			Note 5: 4	D			
	all Organ: breast, thyroid	, teste	S					
Note 7: Elas	tograpny							
			/D: :::	0:	O(t)			
		Б	`	on Sign	,			
				_	cal Health			
	Office of	In Vit	ro Diagno	ostic and	d Radiolog	ical Health		
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Transducer: 8P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	ode o	of Opera	tion	-		-	
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
Candian	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	lication; P = previo er Combined includes: B Power Doppler/PWD ue Harmonic Imaging. T Note 4: 3D Il Organ: breast, thyroid, tography	/M; I	3/PV eatu	ND; B/Ti re does	HI; M/Co	lor M; B/Co contrast ag		
	Office of 510(I	In \		on of Ra Diagno	_	cal Health	ical Health	

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Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	ode o	of Opera	tion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,6
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)			_		_			
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Vessel	Cerebral vascular								
	I .								l

Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Vessel	Cerebral vascular								
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	lication; P = previo er Combined includes: B Power Doppler/PWD ue Harmonic Imaging. T Note 4: 3D all Organ: breast, thyroid tography	/M; i	B/PV eatu	VD; B/Ti re does	HI; M/Co	lor M; B/Co contrast age	11 /		
		In \	/itro	on of R	ostic and	cal Health	ical Health		

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Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	de d	of Opera	ition				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,6
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Vessel	Cerebral vascular								

N = new indication;	P = previo	usly cl	eared by	/ FDA;	E = ad	ded under th	nis appendix	(
Note 1: Other Combined	l includes: B/	M; B/P	ND; B/T	HI; M/Cc	olor M; B/Co	olor Doppler; I	B/Color Dopp	oler/PWD
B/Power Dopple								
Note 2: Tissue Harmonio	ટ Imaging. Th	ne featu	re does	not use	contrast age	ents		
Note 3: TDI	Note 4: 3D			Note 5: 4	ID			
Note 6: Small Organ: bre	east, thyroid,	testes						
Note 7: Elastography								
			(Divisi	on Sign	Off)			
		Divio	•	•	ical Health			
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	Office of	in Vitro	ום מagno	ostic and	a Kadiolog	ical Health		

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510(k) <u>K142710</u>

Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	ode o	of Opera	tion	-		-	
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,6
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardina	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Vessel	Cerebral vascular								

vessei	Cerebral vascular							
N = new inc	lication; P = previ	ously c	eared by	FDA;	E = ad	ded under th	is appendix	
	er Combined includes: E	/M; B/F	WD; B/TI	H; M/Co	lor M; B/Cc	lor Doppler; E	3/Color Dopp	oler/PWD;
	ower Doppler/PWD							
Note 2: Tiss	ue Harmonic Imaging. ٦	he feat	ure does	not use o	contrast ag	ents		
Note 3: TDI	Note 4: 3D		1	Note 5: 4	.D			
Note 6: Sma	II Organ: breast, thyroic	, testes						
Note 7: Elas	tography							
								
			`	on Sign	,			
		Divis	sion of R	adiologi	cal Health			
	Office of	In Vitr	o Diagno	stic and	d Radiolog	ical Health		
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510(k) <u>K142710</u>

Transducer: L752 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	ode o	of Opera	tion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,6,7
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)			_		_			
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Vessel	Cerebral vascular								
	ı								l

Vessel	Cerebral vascular						
Note 1: Othe B/P Note 2: Tissi Note 3: TDI Note 6: Sma	lication; P = previo er Combined includes: B Power Doppler/PWD ue Harmonic Imaging. T Note 4: 3D Ill Organ: breast, thyroid	/M; B/P	WD; B/Ti ure does I	HI; M/Co	olor M; B/Co contrast ag	olor Doppler; E	
Note 7: Elas	tography						
	Office of		ion of R	•	cal Health	ical Health	
	510(I	<)	K14	<u> 12710</u>			

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Transducer: 10L1 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мс	de d	of Opera	tion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,6
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
0 "	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Vessel	Cerebral vascular								,

	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2,
Vessel	Cerebral vascular								
Note 1: Othe B/F Note 2: Tiss Note 3: TDI Note 6: Sma Note 7: Elas	all Organ: breast, thyroid, stography Office of	M; in the feature of	3/PV eatu tes	VD; B/TI re does (Division on of R Diagno	HI; M/Co not use o Note 5: 4 on Sign adiologi	Off) cal Health	olor Doppler;	B/Color Dop	opler/PWD
Indiantiana	torlloo							Dogo 17	a+ 70

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Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Clinical App									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Other	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)			_					
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Cardiac Adult								
	Cardiac Pediatric								
Candiaa	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								
Note 2: Tiss Note 3: TDI	Power Doppler/PWD ue Harmonic Imaging. T Note 4: 3D all Organ: breast, thyroid tography				not use Note 5: 4	_	ents		
	Office of	In \	/itro	on of R Diagno	_	cal Health	jical Health		
Indications	•	/_						Page 18	of 28

Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

	lication								
Clinical App General	lication	IVIC	oae o	of Opera	tion		Power	1	Other*
(TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	(Amplitude) Doppler	Other* Combined	Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Other	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)								
Calulac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Cardiac	intravascular(Cardiac)							
Cardiac	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
N = new inc	lication; P = previo	usly cl	eared by	y FDA;	E = ad	ded under th	nis appendix	(
Note 1: Othe	er Combined includes: B	/M; B/P	WD; B/T	HI; M/Cd	olor M; B/Co	olor Doppler;	B/Color Dopp	pler/PWD
B/F	Power Doppler/PWD							
Note 2: Tiss	ue Harmonic Imaging. T	he feat	ure does	not use	contrast ag	ents		
Note 3: TDI	Note 4: 3D			Note 5: 4	1D			
Note 6: Sma	all Organ: breast, thyroid	testes						
Note 7: Elas	-							
	0 1 7							
			(Divisi	on Sign	Off)			
		Divis	`	_	ical Health			
	Office of			_		ical Health		
	510(I	<)	K1	42710		 		
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Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Other	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)			_					
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

								l
	Other (specify)							
Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	all Organ: breast, thyroid	/M; i	B/PV eatu	VD; B/TI re does	HI; M/Cc	olor M; B/Co contrast ag	olor Doppler; I	
	Office of 510(In \		on of R	ostic and	cal Health	ical Health	

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Transducer: BCC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App		Power Other							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Other	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Cardiac Adult								
	Cardiac Pediatric			_					
Cardiaa	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

	intia oaratao							
	Other (specify)							
Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	Ill Organ: breast, thyroid	/M; Î	B/PV eatu	VD; B/TI re does	HI; M/Cc	olor M; B/Co contrast ag	olor Doppler; I	
	Office of 510(I	In \	/itro	on of R	ostic and	ical Health	i jical Health	

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Transducer: BCL10-5 Biplane Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	al Application Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
Other	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2,4
	Cardiac Adult								
	Cardiac Pediatric			_					
Candina	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

								l
	Other (specify)							
Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	all Organ: breast, thyroid	/M; i	B/PV eatu	VD; B/TI re does	HI; M/Cc	olor M; B/Co contrast ag	olor Doppler; I	
	Office of 510(In \		on of R	ostic and	cal Health	ical Health	

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Transducer: MPTEE Phased Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Mode of Operation									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
0 "	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Peripheral	Peripheral vessel						
Vessel	Cerebral vascular						
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	ll Organ: breast, thyroid	/M; B/P\	WD; B/Ti	HI; M/Co	lor M; B/Co contrast age		
	Office of	In Vitro	ion of R Diagno	_	cal Health	ical Health	

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Transducer: MPTEE mini Phased Array

Diagnostic Ultrasound Transducer

Clinical App	lication	Мс	de d	of Opera	tion			-	
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Imaging& Tran Other Tran	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
0!!	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

Peripheral	Peripheral vessel							
Vessel	Cerebral vascular							
Note 1: Othe B/F	dication; P = preview Combined includes: Power Doppler/PWD ue Harmonic Imaging. Note 4: 3D	B/M; B/P Γhe featι	WD; B/T	HI; M/Cc	olor M; B/Co contrast ag			
	all Organ: breast, thyroic		'	NOIE 3. 4	·D			
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Transducer: CWD2.0

Diagnostic Ultrasound Transducer

Clinical App	lication	Мс	de d	of Opera	tion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult				N				
	Cardiac Pediatric			_	N	_			
Cardiaa	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	all Organ: breast, thyroid,	M; I	B/P\ eatu	ND; B/TI re does I	HI; M/Co	olor M; B/Co contrast ag D	olor Doppler; I		
	Office of			on of R	_	cal Health	ical Health		
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Transducer: CWD5.0

Diagnostic Ultrasound Transducer

Clinical App		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic	_							
	Pediatric	-							
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric				N				
Candiaa	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel				N				
Vessel	Cerebral vascular								

	(-1							l	
Peripheral	Peripheral vessel				N				
Vessel	Cerebral vascular								
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	all Organ: breast, thyroid	'M; I	3/P\ eatu	ND; B/TI	HI; M/Co	lor M; B/Co contrast ag	olor Doppler; I		
		In \	/itro	ion of R	ostic and	cal Health	jical Health		
Indications	,	`/		IXI	12110			Page 26 o	of 28
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Transducer: PWD2.0

Diagnostic Ultrasound Transducer

Clinical App	Clinical Application Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
_	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic			N					
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular			N					

	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular			N					
Note 1: Othe B/F Note 2: Tiss Note 3: TDI	all Organ: breast, thyroid stography ——— Office of	/M; he for , tes	B/PV eatu ites ivisi	VD; B/Thre does	not use on Note 5: 4	olor M; B/Coccontrast ag	olor Doppler; l		
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Indications	for Use							Page 27	of 28

Transducer: LAP7 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Mode of Operation									
	lication	IVIC	de d	ot Opera	tion		D	1	041*
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic	N	N	N		N	N	Note 1	Notes 2,4
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
Fetal	Adult Cephalic								
Imaging&	Trans-rectal								
Other	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
	Cardiac Adult								
	Cardiac Pediatric								
Cordina	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								

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Peripheral	Peripheral vessel								
Vessel	Cerebral vascular								
N = new inc	lication; P = previo	usl	y cle	eared by	FDA;	E = ad	ded under th	is appendix	
	er Combined includes: B	/M;	B/P\	ND; B/TI	H; M/Co	olor M; B/Co	lor Doppler; E	3/Color Dopp	oler/PWD;
	Power Doppler/PWD								
	ue Harmonic Imaging. T		eatu				ents		
Note 3: TDI				1	Note 5: 4	·D			
Note 6: Sma	ıll Organ: breast, thyroid	, tes	tes						
Note 7: Elas	tography								
				/Divicio	n Sign	Off)			
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510(k) Summary

1. Submitter [21 CFR807.92 (a) (1)]

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Date Prepared September 18, 2014

2. Device [21 CFR807.92 (a) (2)]

Trade Name: S9 Portable Digital Color Doppler Ultrasound System
Common Name: Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Classification Panel: Radiology

Device Class: II

3. Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate devices within this submission are as follows:

SonoScape S9 Portable Digital Color Doppler Ultrasound System	K131088
SonoScape S8 Exp Portable Digital Color Doppler Ultrasound System	K132768
SonoScape S30 Digital Color Doppler Ultrasound System	K132527
Philips EPIQ Diagnostic Ultrasound System	K132304
Philips CX50 3.0 Diagnostic Ultrasound System	K123754

4. Device Description [21 CFR 807.92(a) (4)]

This SonoScape S9 Portable Digital Color Doppler Ultrasound System is an integrated

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preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array with a frequency range of 2.0 MHz to 15.0 MHz. This system consists of a portable console with keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a portable, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, 3D/4D.

The subject of this submission is the addition of new indications, new probes and special function to original SonoScape S9.

New indications Trans-esoph.(Cardiac), Cerebral Vascular and Laparoscopic.

Add C542, C613, L743, 10L1, 2P2, 3P1, 5P2, 8P1, EC9-5, BCC9-5,

New probes BCL10-5, MPTEE, MPTEE mini, CWD2.0, CWD5.0, PWD2.0 and

LAP7 probes.

Special function Elastography.

5. Intended Use [21 CFR 807.92(a) (5)]

The SonoScape S9 system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.

6. Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]

S9 Portable Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate devices:

SonoScape S9 Portable Digital Color Doppler Ultrasound System K131088 SonoScape S8 Exp Portable Digital Color Doppler Ultrasound System K132768

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SonoScape S30 Digital Color Doppler Ultrasound System	K132527
Philips EPIQ Diagnostic Ultrasound System	K132304
Philips CX50 3.0 Diagnostic Ultrasound System	K123754

Intended Use Comparison:

Compared with SonoScape S30 (K132527), the Subject Device S9 has the same intended uses except for Laparoscopic indication which is comparable and equivalent to the Predicate Device Philips CX50 3.0 (K123754) and Cerebral Vascular indication which is comparable and equivalent to the Predicate Device Philips EPIQ (K132304). The detailed analysis can be found in the probes comparison.

Technical Characteristics Comparison:

The basic and main technical features of the Subject Device S9 are the same as the original SonoScape S9 (K131088), including Design, Operation Controls, Display Modes, Measurement Items, Cine Loop, Power Supply, Operating and Storage Condition and Screen Size. For Operation Modes, Elastography is a special Operation Mode for the Subject Device S9, but already employed by many marketed devices and considered Substantially Equivalent to the Predicate Device Philips EPIQ (K132304) and detailed comparison analysis can be found in *Substantial Equivalence Comparison*. The detailed technical features can be found in *General Device Descriptions* of the submission.

Probes Comparison:

Subject device S9 has the similar probes as the predicated device SonoScape S8 Exp (K132768), SonoScape S30 (K132527), Philips EPIQ (K132304) and Philips CX50 3.0 (K123754).

Table 1 Probes Comparison

Subject device SonoScape S9	Predicate Device SonoScape S8 Exp	Remark
C322 Micro-curved Array	C322 Micro-curved Array	
C344 Curved Array	C344 Curved Array	
C353 Curved Array	C353 Curved Array	Same
C542 Curved Array	C354 Curved Array	Same
	C362 Curved Array	
	C542 Curved Array	
VC6-2 Curved Array	VC6-2 Curved Array	Same
C613 Micro-curved Array	C611 Micro-curved Array	SE
	C311 Micro-curved Array	Analysis1a)
2P2 Phased Array	2P1 Phased Array	Same

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3P1 Phased Array	2P2 Phased Array	
5P2 Phased Array	3P1 Phased Array	
8P1 Phased Array	5P1 Phased Array	
	5P2 Phased Array	
	8P1 Phased Array	
L741 Linear Array	L741 Linear Array	
L742 Linear Array	L742 Linear Array	
L743 Linear Array	L743 Linear Array	Same
L752 Linear Array	L752 Linear Array	
10L1 Linear Array	10L1 Linear Array	
6V1 Micro-curved Array	6V1 Micro-curved Array	
6V3 Micro-curved Array	6V3 Micro-curved Array	
EC9-5 Micro-curved Array	EC9-5 Micro-curved Array	Same
BCC9-5 Micro-curved Array	BCC9-5 Micro-curved Array	Same
BCL10-5 Biplane (Curved +	BCL10-5 Biplane (Curved +	
Linear Array)	Linear Array)	
Subject device	Predicate Device	Remark
SonoScape S9	SonoScape S30	Roman
MPTEE Phased Array	MPTEE Phased Array	
(Multi-plane)	(Multi-plane)	Same
MPTEE mini Phased Array	MPTEE mini Phased Array	
(Multi-plane)	(Multi-plane)	
Subject device	Predicate Device	Remark
SonoScape S9	Philips CX50 3.0	
CWD2.0, 2.0 MHz	D2cwc, 2.0 MHz	
CWD5.0, 5.0 MHz	D5cwc, 5.0 MHz	SE
Continuous Wave Doppler	Continuous Wave Doppler	Analysis1b)
		- /
LAP7, Linear Array, 10.0-5.0	L10-4 lap, Linear Array, 10.0-4.0	
MHz	MHz	
MHz Subject device	MHz Predicate Device	Remark
MHz Subject device SonoScape S9	MHz Predicate Device Philips EPIQ	
MHz Subject device	MHz Predicate Device	Remark SE Analysis1c)

SE Analysis 1:

- a) Compared with the predicate device SonoScape S8 Exp (K132768), there is a new probe (C613) for the subject device. And the frequency, performance and clinical application of C613 probe are the same as C611 for predicate device.
- b) Compared with the predicate device Philips CX50 3.0 (K123754), the frequency and clinical application of CWD2.0 and CWD5.0 probe is the same as D2cwc and D5cwc cleared for use with predicate device; the clinical application of LAP7 probe is the same

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as L10-4 lap cleared for use with predicate device, and though the frequency of them is different, they both meet the clinical use.

c) Compared with the predicate device Philips EPIQ (K132304), the frequency and clinical application of PWD2.0 probe is the same as D2tcd cleared for use with predicate device.

Note: detailed description information about the new probes can be found in **Substantial Equivalence Comparison**.

Moreover, compared with predicated devices, the subject device (S9) complies with the same regulation and safety standards and has the consistent acoustic output levels. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

7. Non-Clinical Tests [21 CFR 807.92(b) (1)]

The S9 Portable Digital Color Doppler Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output.

Laboratory tests were conducted to verify that the S9 system met all design specifications and the S9 system conformed to applicable medical device standards.

Phantom test was conducted to verify that the strain Elastography function was effective and Elastography performance met design specifications, including accuracy and repeatability of strainratio measurement and etc.

The S9 system has been designed and manufactured to meet the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5, ISO10993-10, UD2, and UD3.

8. Clinical Test [21 CFR 807.92(b) (2)]

No clinical testing was required.

9. Substantially Equivalent Conclusions [21 CFR 807.92(b) (3)]

In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S9 Portable Digital Color Doppler Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.

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